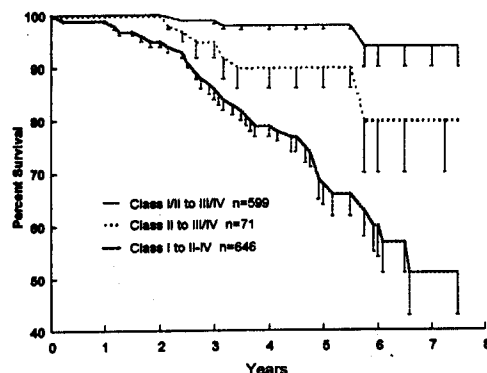


7.5 years after implantation, respectively. Because cardiac perforation with Class II fractures cannot occur, we can regard Class II as equivalent to Class I. Overall progression from this plateau of Class I and II combined to Class III or IV was 0%, 3%, and 7% at 2, 4, and 6 years after implantation. Once a Class II fracture had occurred, progression was 0%, 9% and 19% at 2, 4, and 6 years after implantation. At almost 8 years after implantation, overall actuarial lead survival without Class III or IV fractures was 93%.



We conclude, therefore, that fractures continue to occur at approximately the same rate, but that progression to the more dangerous Class III and IV levels is relatively infrequent. Continued surveillance is indicated.

2:15

717-2 Continued Mortality and Morbidity Associated with the Teletronics Accufix Atrial J-Wire Pacemaker Lead Following Recall: Implications for Management of a Device Failure

D. Kawanishi, J. Brinker, R. Reeves, C. Love, A. Rozkovec, G. Pioger, G.N. Kay, M. Mutter, J.-C. Petitot, N. Goldschlager, J. Fee. *University of Southern California, Los Angeles, CA, USA, Teletronics Accufix Advisory Committee, Denver, CO, USA*

In order to record the number and causes of injuries due to the Teletronics Accufix atrial lead j-wire fracture or attempts to extract the lead, all reports were confirmed when possible by review of records, imaging studies, operative findings, and recovered leads.

Results: Fatalities: Of 5 due to wire fracture, 4 occurred before or at the time of recall; 1 occurred subsequently in 1/96, the patient died in the emergency room; 8 resulted from extraction attempts. Nonfatal injuries: 24 from j-wire fracture, 61 with extraction.

| | Injury from J-Wire Fracture | | | | Injury from Lead Extraction | | | |
|----------------------|-----------------------------|-------|-----|----------------|-----------------------------|-------|-------|-----------------|
| | Pts | Age | M/F | Lead Status | Pts | Age | M/F | Lead Status |
| Death | 5 | 26-83 | 2/3 | 5 = protruded | 8 | 60-92 | 2/6 | 6 = no fracture |
| Tamponade | 13 | 21-88 | 7/6 | 13 = protruded | 4 | 46-78 | 1/3 | 2 = no fracture |
| Pericard. Effusion | 5 | 54-75 | 1/4 | 5 = protruded | 5 | 32-71 | 1/4 | 3 = no fracture |
| Atrial Perforation | 2 | 17-56 | 2/0 | 2 = protruded | 2 | 45-80 | 0/2 | 2 = no fracture |
| Embolism | 3 | 56-67 | 2/1 | 4 = embolized | | | | |
| Hemopneumothorax | | | | | 7 | 23-87 | 2/5 | 4 = fractured |
| Vascular Injury | | | | | 11 | 33-89 | 5/6 | 11 = fractured |
| Elective Thoracotomy | | | | | 24 | 23-83 | 14/10 | 15 = fractured |

Conclusions: Optimal management of an implantable device recall should consider: 1. Widespread and high-level awareness of the device failure and its injury potential is necessary; 2. That potential must be balanced against injury from device removal.

2:30

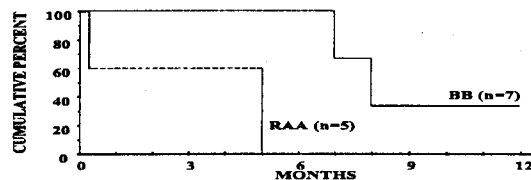
717-3 A Prospective Randomized Trial of Bachmann's Bundle Pacing for the Prevention of Atrial Fibrillation

S.J. Bailin, W.B. Johnson, R. Hoyt. *Iowa Heart Center, Des Moines, Iowa, USA*

We have previously reported that acute pacing from the anterior interatrial septum in the region of Bachmann's bundle (BB) results in reduced P wave duration and more symmetric atrial activation. In order to determine if these effects would impact the recurrence rate of AF, we randomized 12 pts who had recurrent AF and an indication for pacing (6 AV Nodal ablation, 6 bradycardia) to either the right atrial appendage (RAA) (5 pts) or BB (7 pts) permanent pacing. Both positions were assessed fluoroscopically. Antiarrhythmic therapy was discontinued upon implantation; nodal blocking agents were permitted. The pacemaker implanted was a Thera, Medtronic with Mode switching (MS)

on. Time to 1st non-sustained AF recurrence as detected by the first MS episode (AFR) and time to chronic AF were evaluated during a mean F/U period of 6.4 months (range 0.5 to 13 months). **Results:**

| | BB (SD) | RAA (SD) | P value (t-test) |
|-----|-----------|-------------|------------------|
| AFR | 0.7 (0.6) | 0.64 (0.24) | 0.4 (NS) |



A significant difference was observed in the time to chronic AF between the two sites. (Wilcoxon chi-square = 4.337 p = 0.0373)

Conclusions: 1) The time to first AFR was not significantly different between the study groups; 2) the time to chronic atrial fibrillation was significantly affected by the site of atrial pacing. The BB group demonstrated improved sinus rhythm survival compared to the RAA group. This result should encourage expanded study of the use of BB pacing for prevention of atrial fibrillation.

2:45

717-4 Does pacemaker implantation have a placebo-effect? Results from the PIC study group

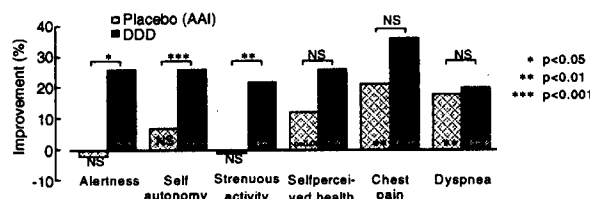
C. Linde, F. Gadler, for the PIC Study Group. *Dept. of Cardiology, Karolinska Hospital, Stockholm, Sweden*

Uncontrolled studies have shown that short AV-delay dual chamber pacing (DDD) improves left ventricular obstruction (LVOT) and relieves symptoms in patients with hypertrophic obstructive cardiomyopathy (HOCM). PIC is a European multicenter, randomised, cross-over study. One of the aims was to document the effects on quality of life (QoL) of DDD-pacing compared to atrial inhibited pacing at 30 bpm (AAI) in HOCM patients and to evaluate a possible placebo-effect of device implantation.

Patients: Eighty-three patients with HOCM were recruited. After a baseline evaluation followed by pacemaker implantation, patients were randomly assigned to 3 months each of AAI or DDD pacing and evaluated after each study period.

Method: The Karolinska questionnaire was used to evaluate QoL in 81 patients. It contains items on all broad domains of QoL. The placebo-effect was defined as QoL_{baseline} - QoL_{AAI} during the first study period (I). It was compared between 40 patients after AAI-I and 41 after DDD-I, respectively.

Results: There was an improvement in QoL for patients paced AAI-I, in particular for symptoms. Patients paced DDD-I improved significantly more than those on AAI-I regarding alertness, self-autonomy and strenuous physical activity (see Fig.).



Conclusion: Pacemaker implantation has a placebo effect in particular for symptomatology. This has to be taken into account when conducting studies of the clinical effects of cardiac pacing.

3:00

717-5 Efficacy and Safety of Coronary Sinus Ostial Pacing for Suppression of Atrial Fibrillation

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While high RA [HRA] pacing has been examined for prevention of recurrent atrial fibrillation [AF], the efficacy of low RA pacing sites has not been studied. We performed coronary sinus ostial [CSOs] pacing alone during crossover periods in a prospective sequential protocol for dual site RA pacing [DAP] (HRA + CSOs) & single site CSOs pacing in drug-refractory AF patients [pts]. We examined arrhythmia-free intervals & incidence of recurrent AF in 14 pts with dual atrial leads & a DDDR pacemaker. Pts were overdrive paced